

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

RALPH SIMON,)	Case No. 4:14-cv-1136 (JAR)
)	
Plaintiff,)	
v.)	REPLY MEMORANDUM OF LAW IN
SELECT COMFORT RETAIL CORP.,)	SUPPORT OF DEFENDANTS'
)	MOTION TO EXCLUDE THE
and)	TESTIMONY OF ERNEST P. CHIODO
SELECT COMFORT CORPORATION,)	
)	
Defendant.)	

To prevail on his claims, Plaintiff must prove through expert testimony to a reasonable degree of medical certainty that his alleged symptoms are caused by the purported mold in his Sleep Number® bed. Plaintiff offers professional expert, Dr. Ernest P. Chiodo,¹ to make this causal connection. Dr. Chiodo's opinions, however, are inadmissible given his failure to perform a scientific differential diagnosis and his clear lack of qualifications to opine on issues in medical specialties in which he has no experience, as detailed in Select Comfort's brief. In response, Plaintiff attempts to bolster Dr. Chiodo's credibility by citing his numerous alma maters in hopes that the Court will forgo an analysis of Dr. Chiodo's actual testimony and qualifications to render opinions in *this* case. The Court need only read Dr. Chiodo's report to see that his conclusions are based on his own unsound reasoning, supposition and speculation—that is, the *ipse dixit* of Dr. Chiodo. Therefore, Dr. Chiodo's opinions are inadmissible under

¹ (Ex. 9 (Chiodo Tr.) 7:12–18; 13:1–12; 15:1–17:7; 146:1–10). Exhibits 1–38 cited herein are attached to the Declaration of Andrew S. Hansen, filed August 28, 2015. Exhibits 39–41 are attached to the Second Declaration of Andrew S. Hansen, filed October 16, 2015. Exhibits 42–46 are attached to the Third Declaration of Andrew S. Hansen, filed October 26, 2015.

Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and must be excluded.

ARGUMENT

I. DR. CHIODO IS NOT AN ALLERGIST AND FAILS TO UNDERTAKE A PROPER DIFFERENTIAL DIAGNOSIS TO OPINE ON CAUSATION.

A. Dr. Chiodo Has No Specialized Knowledge In Diagnosing Or Treating Allergies.

This is not a “sick building syndrome” case nor is it a case in which Plaintiff is claiming exposure to a “toxic” substance. Therefore, Dr. Chiodo’s much-emphasized experience and board certifications related to toxicology and environmental health are inapposite here. What this is, however, is a case in which Plaintiff claims that exposure to a common indoor and outdoor mold has caused him to suffer from allergic symptoms that, in turn, have caused additional complications. Thus, the pertinent area of medical inquiry is allergy/immunology. (Defs.’ Br. at 4.) It is undisputed that Dr. Chiodo has no specialized training or education in allergic medicine, and he is therefore not qualified to opine on the cause of Plaintiff’s symptomology. (*Id.* at 4.)

Plaintiff suggests that any physician, no matter the experience, can testify regarding any medical issue. (Pl.’s Opp’n at 4.) Relying on *Robinson v. GEICO General Insurance Co.*, 447 F.3d 1096 (8th Cir. 2006) and *Isham v. Booneville Community Hospital*, No. 2:14-cv-02018, 2015 WL 3965701 (W.D. Ark. June 30, 2015), Plaintiff argues that a physician with “general knowledge” may testify regarding medical issues that a specialist might treat. (Pl.’s Opp’n at 4.) That oversimplifies and incorrectly states the law. Courts have permitted a physician to testify regarding medical issues that a different specialist might treat *only* when the physician has demonstrated specific experience that makes the physician particularly qualified to testify regarding the particular medical area at issue.

For example, in *Robinson v. GEICO General Insurance Co.*, a neurologist testified regarding the nerve supply in the shoulder and the usual onset of shoulder pain. 447 F.3d at 1101. The plaintiff challenged the neurologist's qualifications to testify regarding the shoulder injury, arguing that he was not an orthopedist and was outside his expertise. *Id.* at 1100. The court held that although the defendant's expert was not an orthopedist, the expert testified within his realm of expertise—that is, a neurologist testified about nerves in the shoulder—and the court held that the testimony was derived from his actual “study of the subject.” *Id.*

In *Isham v. Booneville Community Hospital*, the plaintiff offered the expert testimony of an oral maxillofacial surgeon who based his opinion on eighteen years of experience as a board certified surgeon and experience dealing with antibiotics, education in both of those areas, and review of relevant literature. *Id.* at *6. The court found that while plaintiff's expert did not have experience with the plaintiff's exact, rare form of cancer, the expert had specific experience with prescribing antibiotics under the circumstances at issue. *Id.*

Unlike *Robinson* or *Isham*, there is no evidence here that Dr. Chiodo has extensive experience treating or studying allergies. Indeed, highlighting Dr. Chiodo's lack of qualifications, Plaintiff chose not to—or could not—defend Dr. Chiodo's clear lack of qualifications illustrated by his stunning failed attempt to interpret the medical results of the allergy skin test performed by Dr. Wedner's office. (Defs.' Br. at 4 (*comparing* Ex. 22 (Wedner Tr.) 63:2–18 *with* Ex. 9 (Chiodo Tr.) 45:4–47:3).) This failure underscores not only Dr. Chiodo's lack of qualification to opine in the area of allergic medication, but also his dangerous refusal to recognize and admit the limits of his own knowledge and expertise.

B. Dr. Chiodo Did Not Perform A Differential Diagnosis.

A properly-conducted differential diagnosis may be scientifically valid for purposes of a *Daubert* analysis; but Dr. Chiodo failed to perform one. To prove that the alleged defective

design of Plaintiff's Sleep Number® bed was the proximate cause of Plaintiff's injuries, "[Plaintiff] must also negate any other reasonable conclusion that may be drawn from the facts." *Willard v. Bic Corp.*, 788 F. Supp. 1059, 1064 (W.D. Mo. 1991) (citing *Zafft v. Eli Lilly & Co.*, 676 S.W.2d 241, 244 (Mo. 1984)). "When conducting a differential diagnosis, the expert physician must *scientifically* eliminate the other potential causes of a plaintiff's condition." *Holloway v. Ameristar Casino St. Charles, Inc.*, No. 4:07CV218, 2009 WL 5169535, at *4 (E.D. Mo. Dec. 18, 2009) (emphasis in original).

1. There Is No Reasonable Basis To "Rule In" Mold Exposure As A Potential Cause Of Plaintiff's Allergic Reactions.

As Select Comfort argued in its initial brief, there is absolutely no basis for Dr. Chiodo to rule *Cladosporium* mold exposure in as a potential cause of Plaintiff's alleged injuries because there is insufficient evidence that Plaintiff was exposed to mold from his bed in the first place. (See Defs.' Mem. Supp. Mot. Excl. Duncan (Doc. No. 57) & Reply (Doc No. 144).)

Plaintiff suggests that Dr. Chiodo will rely on Patsy Duncan's report and Rule Federal Rule of Evidence 703 to infer that mold was present while Plaintiff was using his Sleep Number® bed. (Pl.'s Opp'n at 8.) But the Duncan Report explicitly states that it is limited in scope to the alleged existence of mold on the foam at the time of Duncan's testing—five months *after* Plaintiff removed the foam from Plaintiff's house, exposed it to the outside air, laid it on the ground, and then sealed it in a plastic bag. Dr. Chiodo is not a microbiologist, nor has Plaintiff otherwise established that Dr. Chiodo is qualified to testify regarding mold in any capacity. According to Plaintiff's expert, mold can grow in as quickly as forty-eight hours. (Ex. 11 (Duncan Tr.) 69:6–70:8.) Thus, the alleged existence of mold at the time of Duncan's testing cannot provide a basis to "infer" that mold existed on the bed five months earlier. Rather, Dr. Chiodo would have needed to employ a reliable methodology to extrapolate on Duncan's test

results. Considering Dr. Chiodo has not identified any scientific methodology for concluding that mold existed on Plaintiff's bed at the time Plaintiff used it, this conclusion is not scientifically reliable, and instead rests on mere speculation and conjecture. *See In re Genetically Modified Rice Litig.*, No. 4:06MD1811, 2010 WL 2326036, at *4 (E.D. Mo. June 7, 2010) ("[An expert] may apply the results of another expert's calculations, *if a foundation is laid showing that they are qualified to do so.*" (emphasis added)); *Heller v. Shaw Industries*, 167 F.3d 146, 162–63 (3rd Cir. 1999) (holding that an expert's extrapolation based on speculation and estimation does not meet the *Daubert* standard). Further, Duncan performed no air sampling, so her report cannot support an inference that Plaintiff was exposed to the alleged mold.

Plaintiff's defense of Dr. Chiodo's purported differential diagnosis is just as deficient as the diagnosis itself. Plaintiff claims Dr. Chiodo questioned Plaintiff regarding his history of hypertension, diabetes, pulmonary disease, etc. (Pl.'s Opp'n at 7.) But Plaintiff ignores Dr. Chiodo's failure to rule in and consider several, obvious alternative causes of his symptoms and, instead, rests his differential diagnosis solely on Plaintiff's proven false self-reported patient history. (Ex. 24 (Wedner Rblt.) at ¶¶ 5–8, 10; Ex. 1 (Simon Tr.) 37:21–38:20.)

Plaintiff also fails to adequately address Dr. Chiodo's deficient physical examination. For example, Dr. Chiodo did not conduct an adequate examination of Plaintiff's nose and throat. (Defs.' Br. at 9.) Plaintiff claims Select Comfort "fail[s] to note" certain vague references in Dr. Chiodo's report regarding symmetrical face movements, normal chewing, normal swallowing and reflexes, and normal tongue movement. (Pl.'s Opp'n at 8.) Considering that Plaintiff's complaints are allergen-based, these cursory notes regarding the outward presentation of the throat are deficient and, of course, reflect no examination of Plaintiff's nose.

Finally, as described below, because there is no legitimate temporal relationship between any alleged exposure to mold and Plaintiff’s onset of allergic symptoms, there is no basis to “rule in” mold as a potential cause of Plaintiff’s reactions.

2. The Alleged “Temporal Relationship” Between Plaintiff’s Symptoms And The Use Of His Bed Is Illusory.

According to Plaintiff, Dr. Chiodo rests his opinion on the “clear temporal relationship” of the mold exposure to Plaintiff’s symptoms and testimony that relies on a temporal relationship “has been looked upon favorably by a number of federal courts.” (Pl.’s Opp’n at 8–9). Dr. Chiodo’s unsupported assumption that a temporal relationship exists between Plaintiff’s use of his Sleep Number® bed and his onset of symptoms is based on circular, unscientific and unsound reasoning and is not supported by the facts. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”); *Heller*, 167 F.3d at 152 (“[A]n expert opinion must be based on reliable methodology and must reliably flow from that methodology and the facts at issue. . . .”).

Dr. Chiodo claims that “[Plaintiff’s] symptomatology matches his duration of sleeping on the moldy bed.” (Ex. 9 (Chiodo Tr.) 51:21–23.) According to Dr. Chiodo, Plaintiff did not show any allergic symptoms in 1999 (*id.* 48:20–49:12), but then in 2002, Plaintiff began presenting “rhinitis and the like” (*id.* 49:19–50:4). Dr. Chiodo claims that after Plaintiff stopped sleeping on the bed, his allergic symptoms were “largely resolved.” (*Id.* 50:4–12.) Dr. Chiodo then concludes that because he is “not aware” of any other diet change or “any other exposure circumstance that matches the temporal sequence of this symptomatology,” he has “ruled out” any other possible sources of Plaintiff’s allergic manifestation. (*Id.* 50:10–51:7.)

When asked what facts in the record he relied on to show that mold was in the bed in 2002, Dr. Chiodo stated that “deductive logic analysis” led him to conclude that mold formed in Plaintiff’s bed sometime in fourteen-year span from 1999 to 2013. (*Id.* 52:4–19.) Yet, Dr. Chiodo provides no basis, other than the alleged onset of Plaintiff’s symptoms, to conclude that mold formed in Plaintiff’s bed in 2002. In short—Dr. Chiodo claims a temporal relationship exists between Plaintiff’s symptoms and alleged mold in his bed in 2002; because Dr. Chiodo concluded mold existed in 2002; because of Plaintiff’s alleged onset of allergic symptoms. This dizzying, circular reasoning is not based on supportable, scientific principles and is inadmissible.

Indeed, the purported temporal relationship is contradicted by facts of which Dr. Chiodo was apparently “unaware.” Plaintiff has offered three different dates that his injuries began, spanning over a seven-year period. Dr. Chiodo, also an attorney, apparently failed to read the complaint in this case alleging that Plaintiff “began experiencing ailments” in “early 2009” and he therefore did not account for that alternate date, which destroys his speculative temporal relationship theory. (Compl. (Doc. No. 5) at 11 ¶ 2; Am. Compl. (Doc. No. 31) ¶ 4.) And Dr. Chiodo must have also failed to review Plaintiff’s prior affidavit, swearing Plaintiff experienced “sudden-onset symptoms” in 2006 (Ex. 32 (Simon Aff.) ¶ 4), as well as Plaintiff’s deposition in this case discussing these discrepancies. Finally, Dr. Chiodo must be unaware that Plaintiff moved homes in 2006, noticing no mold on the bed during his move, began construction to make improvements to his new home, and began caring for his mother’s dog. (Ex. 1 (Simon Tr.) 9:17–11:24; 24:4–14; 25:18–26:21.) Interestingly, one of the improvements Plaintiff made to his new home was to rip out and replace some, but not all, of the old carpet. (*Id.* at 10:17–11:3.) See *Heller*, 167 F.3d at 157–58 (alleging inhalation of VOCs from new carpet caused personal

injuries).² These undisputed facts negate the temporal relationship that Dr. Chiodo relies upon. *See Heller*, 167 F.3d at 158 (“Here, however, we have no problem concluding that the temporal relationship between the exposure to the Shaw carpeting and the onset of Heller’s illness was questionable at best and exculpatory at worst.”)

Dr. Chiodo claims his “differential diagnosis” is also based on the conclusion that Plaintiff’s symptoms “largely resolved, not completely resolved, after he discovered the mold contamination of his bed, and then stopped sleeping on the mold-contaminated bed.” (Ex. 9 (Chiodo Tr.) 50:4–10.) But the fact is, Plaintiff had not seen his otolaryngologist treating physician, Dr. Craig, for his symptoms for almost a year *before* he removed the bed from his home, suggesting that Plaintiff’s condition had already been improving before he discovered the alleged mold. (Ex. 43 (Craig Tr.) 108:22–109:14; 111:21–112:2.) Likewise, according to Plaintiff’s physician, Plaintiff requested a prescription for Gentamycin on December 9, 2014—nineteen months after Plaintiff’s bed was removed from his home, suggesting that his symptoms did not largely resolve after he discovered the alleged mold, as Dr. Chiodo concludes. (*Id.* 129:9–19.) Simply put, Plaintiff’s own medical records undercut Dr. Chiodo’s conclusion that Plaintiff’s symptoms were temporally related to his bed.

3. Dr. Chiodo Failed to Rule Out Other Obvious Causes.

Plaintiff claims that Dr. Chiodo need not consider all possible causes in the record but does not address Dr. Chiodo’s complete failure to consider and rule out other obvious causes. (Pl.’s Opp’n at 7.) Plaintiff’s entire claim rests on alleged injuries that stem from an alleged allergic reaction to *Cladosporium* mold. As evidenced by his undisputed allergy skin testing performed by Dr. Wedner, Plaintiff is a highly atopic individual and has sensitivities to

² Even though Plaintiff admits that he knows that “all carpet has allergens in it” (*id.* at 71:21) he admits that he has never had his home assessed for potential allergens (*id.* at 71:10–18).

numerous allergens. (Ex. 23 (Wedner Rpt.) at 6–7.) In addition to *Cladosporium*, he is allergic to at least thirty-six different allergens:

[Plaintiff] is sensitized to white ash, birch mix, elm mix, red willow, Kentucky blue grass, brome grass, Johnson grass, Timothy grass, cocklebur, Lambs Quarters, true marsh elder, spiny pigweed, English plaintain, *Curvularia*, *Epicoccum*, *Geotrichum*, *Helminthosporium*, *Hormodendrum*, *Penicillium*, *Candida albicans*, corn smut, Johnson smut, wheat smut, *Trichophyton*, cat, mouse and *Stachybotrys*. The patient also had a series of intradermals done which showed sensitivity to *Alternaria*, *Aspergillus*, *Aspergillus fumigatus*, *Cladosporium*, *Fusarium*, *Phoma beta*, *Spondylocladium*, *Stemphyllium*, dust mite DP and dust mite DF.

(Ex. 23 (Wedner Rpt.) at 6.) Despite the fact that Dr. Craig testified that there are “a lot of allergies in St. Louis,” (Ex. 3 (Craig Tr.) 90:8–9), there is no evidence, either in Dr. Chiodo’s report or his deposition testimony, that Dr. Chiodo did any analysis to determine whether Plaintiff was exposed to any of these additional potential allergens or to rule them out. *See Roche v. Lincoln Prop. Co.*, 175 Fed. App’x 597, 602–3 (4th Cir. 2006) (excluding medical expert in mold exposure case not an abuse of discretion where expert failed to apply differential diagnosis by failing to exclude any other non-mold allergens to which plaintiffs were sensitive).

When asked if he did anything to rule out symptoms caused by allergies to other substances, Dr. Chiodo claimed he did based merely on “[t]he history from [Plaintiff] and review of the records.” (Ex. 11 (Chiodo Tr.) at 47:25–48:12.) Dr. Chiodo claims he did not need to conduct an allergy test, because what matters is what Plaintiff *says* he is allergic to and Dr. Chiodo did not see “any sign of a lack of truthfulness on his part.” (Ex. 11 (Chiodo Tr.) at 41:18–42:11.) But when conducting a differential diagnosis, “the expert physician must *scientifically* eliminate the other potential causes of a plaintiff’s condition.” *Holloway*, 2009 WL 5169535, at *4 (E.D. Mo. Dec. 18, 2009) (differential diagnosis based on history provided by party did not follow the differential diagnosis procedure). “The expert physician cannot eliminate causes based simply on the patient’s credibility.” *Id.*

Likewise, when asked if he ruled out dust mites, in particular, as a possible cause of Plaintiff's allergic reaction, Dr. Chiodo reasoned that “[d]ust mites would have been part of his environment before the bed” and “after the time duration that he’s sleeping on [his bed].” (Ex. 9 (Chiodo Tr.) 51:8–23.) Thus, according to Dr. Chiodo, the temporal relationship does not fit with an allergy to dust mites. (*Id.*) But this is precisely the flaw with the alleged temporal relationship between Plaintiff’s alleged exposure to *Cladosporium* mold in his bed and his purported onset of symptoms. It is irrefutable that Plaintiff was, and continues to be, exposed to *Cladosporium* mold on a constant, daily basis in varying doses. *Cladosporium* is “the most frequently found genus of fungi in outdoor air in temperature climates.” (See Ex. 12 (Duncan Rpt.) 15; Ex. 19 (Pastore Tr.) 19:1–9; Ex. 22 (Wedner Tr.) 82:14–22 (“There was a day three or four years ago in which [St. Louis] set the world record for spores [of *Cladosporium herbarum*] per cubic meter at 130,000 or 142,000.”).)³ Therefore, if *Cladosporium* mold was the cause of his allergic symptoms, as Plaintiff claims, he would continue to suffer those symptoms on an ongoing, daily basis to this day. “A failure to consider alternative potential causes” renders Dr. Chiodo’s differential diagnosis “scientifically invalid.” *Tedder v. Am. Railcar Industr., Inc.*, 739 F.3d 1104, 1109 (8th Cir. 2014); *see, e.g., Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006) (affirming exclusion of a toxicologist on medical causation where the toxicologist did not exclude confounding factors leaving open the possibility of competing causes); *Parmentier v. Novartis Pharms. Corp.*, No. 1:12-cv-45, 2012 WL 2326047, at *4 (E.D. Mo. June 19, 2012) (excluding expert testimony that “failed to rule out several known causes”); *Paige v.*

³ Select Comfort’s expert conducted both surface and air sampling of Plaintiff’s frequented environments, including his home (without the purported contaminated foam), his place of worship, and his office. (Ex. 16 (Hemming Rptr.) at 3–5, ¶ 1.) The results show that Plaintiff comes into contact with various fungal and bacterial organisms, including *Cladosporium*, at all of these locations. (*Id.* at 4–5.)

Harper, No. 1:06CV111, 2010 WL 145156, at *4 (E.D. Mo. Jan. 8, 2010) (“Even if [Plaintiff’s experts] were able to link Plaintiff’s alleged exacerbated asthma to pepper spray inhalation, they must also rule out other possible causes.”).

Plaintiff relies on *Heller v. Shaw Industries, Inc.*, 167 F.3d 146 (3rd Cir. 1999) for the proposition that a physician need not conduct every possible test and rule out all possible causes in order to apply a proper differential diagnosis. (Pl.’s Opp’n at 8.) In *Heller*, the Third Circuit explained an expert need not “rule out every possible alternative,” but must engage in a differential diagnosis that is reliably applied and rules out “obvious alternative causes.” *Heller*, 167 F.3d at 156; see *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 694 (8th Cir. 2001) (an expert must “discount[] obvious alternatives through scientific testing”); see, e.g., *Jenkins v. Slidella LLC*, No. 05-370, 2008 WL 2649510, at *4 (E.D. La. June 27, 2008) (“Plaintiffs’ symptoms could be caused by any number of other exposures and/or conditions [Plaintiffs’ expert] failed to perform a differential diagnosis adequate to explain why exposure to Aspergillus mold at Plaintiffs’ apartment ‘is the most probable cause of the Plaintiffs’ complaints.’”). In *Heller*, unlike here, the plaintiff’s expert ordered standard laboratory tests, conducted a thorough physical examination, and considered alternative causes of the plaintiff’s illness. 167 F.3d at 156. “Accordingly, [Dr. Chiodo’s] conclusion on causation does not assist the trier of fact, and must be excluded.” *Holloway*, 2009 WL 5169535, at *4.

II. DR. CHIODO IS NOT AN OPHTHALMOLOGIST, HAS NO EXPERIENCE OR TRAINING REGARDING CATARACTS, AND FAILED TO PERFORM A DIFFERENTIAL DIAGNOSIS REGARDING PLAINTIFF’S CATARACTS.

It is undisputed that Dr. Chiodo is not an ophthalmologist, nor has he cited any specialized training or experience which would allow him to diagnose cataracts or their causes. In fact, similar to his experience with the skin test results, Dr. Chiodo was asked at his deposition whether he was familiar with the Lens Opacity Classification System (LOSC) (Ex. 9 (Chiodo

Tr.) 86:10–12), which is the most commonly used standard system for determining cataract types (nuclear sclerosis cataract, cortical cataract, or posterior subcapsular cataract) and grading opacities of cataracts. (Ex. 21 (Sher Rpt.) at 2, 4–5; Ex. 44) *See also* Nino Hirnschall & Oliver Findl, *Patient-assessment Techniques for Cataract Surgery*, 6 EXPERT REV. OF OPHTHALMOLOGY 211 (2011) (“The most common method to grade cataract is the Lens Opacities Classification System III. . . .”). Dr. Chiodo was not familiar with LOCS and was not aware how it was “germane to th[e] issue.” (Ex. 9 (Chiodo Tr.) 86:13–17.) Therefore, Dr. Chiodo is not qualified to diagnose or opine on the causation of cataracts.

Further, Dr. Chiodo’s ignorance also unravels his purported opinion. The academic literature Dr. Chiodo relies upon in support of his cataracts causation theory found a high dose-related relationship between steroid use and *posterior subcapsular cataracts*, which is only one type of cataract. (Ex. 10 (Chiodo Rpt.) at 35; *see* Ex. 21 (Sher Rpt.) at 6–7.) Plaintiff’s medical records reflect Plaintiff *does not have* posterior subcapsular cataracts, which Dr. Chiodo does not dispute. (Ex. 21 (Sher Rpt.) at 7.) Therefore, his sole reliance on that single article is misplaced.

Plaintiff fails to address the fact that the scientific literature does not support Dr. Chiodo’s opinion. *See Mack v. Stryker Corp.*, 748 F.3d 845, 851–54 (8th Cir. 2014). Instead, Plaintiff attempts to deflect this issue by characterizing it as a difference of opinion between experts. (Pl.’s Opp’n at 12.) But in the absence of certification or experience as an ophthalmologist, and without some medical basis to support a conclusion that Prednisone can indeed cause posterior subcapsular cataracts, it was pure guesswork to rule Prednisone in as a possible cause of Plaintiff’s cataracts. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (excluding diagnosis because physicians lacked a proper basis for “ruling in” Paraldol in the first place).

Finally, Dr. Chiodo's failure to undertake a proper differential diagnosis is highlighted by his failure to rule out obvious causes of Plaintiff's type of nuclear sclerosis cataracts, including age and heredity. (Ex. 21 (Sher Rpt. at 6).) This failure is even more acute when considering that Plaintiff has a family history of cataracts. (Ex. 45 (K. Driskill Tr.) 11:4–5; 30:8–13.)

III. DR. CHIODO IS NOT AN OTOLARYNGOLOGIST, HAS NO EXPERIENCE WITH HEARING LOSS, NO EXPERIENCE PRESCRIBING GENTAMYCIN, AND FAILED TO PERFORM A DIFFERENTIAL DIAGNOSIS REGARDING PLAINTIFF'S HEARING LOSS.

Plaintiff does not dispute that the literature cited by Dr. Chiodo does not support his causation theory and instead claims that, in the absence of an authoritative document stating that proposition, the parties are simply proffering experts who have differing opinions. (Pl.'s Opp'n at 10.) The notion of requiring a defendant to offer an authoritative document to prove a negative is illogical. Moreover, Plaintiff's treating otolaryngologist, Dr. Craig, disagrees with Plaintiff's assertion that intranasal Gentamycin put Plaintiff at risk for hearing loss. (Ex. 43 (Craig Tr.) 160:25–161:19.) There is no scientific support for Dr. Chiodo's causation theory.

Plaintiff now claims Dr. Chiodo's opinion that Gentamycin causes ototoxicity is “primarily based upon his knowledge, training, and experience” (Pl.'s Opp'n at 11) and that Dr. Chiodo is not required to cite published studies regarding general causation. While it is true that an expert need not always cite published studies to support a causation theory, the theory must be based on *something*. See *Mack*, 748 F.3d at 851–54 (finding medical literature did not support expert's conclusions); *Glastetter*, 252 F.3d at 989 (excluding diagnosis because physicians lacked a proper basis for “ruling in” Paraldol in the first place). For example, in *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038 (2d Cir. 1995), cited by Plaintiff, the court determined that a certified otolaryngologist had a background sufficient to permit his expert testimony on a throat ailment and its causes, despite the fact that there was no published literature to support his

opinions. *Id.* at 1043. Dr. Chiodo, however, is not an otolaryngologist and has no such specific background, certifications, knowledge or experiences that would allow him to offer unsupported theories regarding Gentamycin causing ototoxicity.

As Select Comfort argues in its initial brief, in concluding that Gentamycin caused Plaintiff's alleged ototoxicity, Dr. Chiodo also neglects the cornerstone of toxicology diagnosis—the dose-response relationship. (Defs.' Br. at 13 (citing claims *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105 (8th Cir. 1996).)) Plaintiff claims, without any legal support, that *Wright v. Willamette Industries, Inc.* is inapposite because it only applies to “toxic tort” cases, whereas this case allegedly involves side effects of a prescription medicine which is a “completely different concept.” (Pl.'s Opp'n at 11.) While Select Comfort agrees that this case, generally speaking, is not a toxic tort case, the definition of ototoxic is “having a toxic action upon the ear.” *Stedman's Medical Dictionary* 1273 (26th ed. 1995). Therefore, allegations that Gentamycin had ototoxic effects is, by definition, a toxic tort that required Dr. Chiodo assess the dose-response relationship for this particular injury.

Finally, Dr. Chiodo also failed to consider the obvious alternative cause that Plaintiff's hearing loss was caused by a viral infection. According to Plaintiff's medical records, Plaintiff told Dr. Craig that he has an existing hearing loss that was diagnosed as caused by a viral infection. (Ex. 43 (Craig Tr.) 75:1–16.) Dr. Chiodo does not explain why he did not consider this obvious alternative cause.

IV. DR. CHIODO IS NOT QUALIFIED TO TESTIFY REGARDING DEFECTIVE DESIGN.

Plaintiff argues that Dr. Chiodo's background as a biomedical engineer makes him qualified to testify regarding the design of Plaintiff's bed. (Pl.'s Opp'n at 5.) First, nowhere in Dr. Chiodo's report does he proffer a single opinion regarding the design of Plaintiff's bed. *See*

Fed. R. Civ. P. 26(a)(2)(B)(i) (requiring an expert report contain “a complete statement of all opinions the witness will express and the basis and reasons for them”); *see also Rembrandt Vision Tech., L.P. v. Johnson & Johnson Vision Care, Inc.*, 725 F.3d 1377, 1381 (Fed. Cir. 2013) (excluding expert testimony because “[a]n expert witness may not testify to subject matter beyond the scope of the witness’s expert report unless the failure to include that information in the report was ‘substantially justified or harmless’”).

Second, a general background in engineering does not render Dr. Chiodo qualified to testify regarding the design of Plaintiff’s bed; rather, an expert must have adequate experience designing or consulting on the design of the product in question. *See, e.g., Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003) (recognizing that “some engineering principles can be applied universally” but affirming the exclusion of engineering expert’s defective design opinion because expert had never designed or consulted on design of product in question); *Krueger v. Johnson & Johnson Prof’l, Inc.*, 66 Fed. App’x 661, 662 (8th Cir. 2003) (holding that exclusion of metallurgist’s expert testimony regarding defective design of a medical device was not an abuse of discretion where expert had insufficient knowledge or experience with the device design); *Shaffer v. Amada Am., Inc.*, 335 F. Supp. 2d 992, 995–96 (E.D. Mo. 2003), *aff’d*, 2003 WL 26129823 (8th Cir. Sept. 18, 2003) (expert did not have appropriate familiarity or design experience with the device in question). Therefore, Dr. Chiodo should be excluded from testifying regarding defective design of the Sleep Number® bed.

CONCLUSION

Plaintiff’s purported expert, Dr. Chiodo is plainly not qualified to render his opinions in this case, and he failed to undertake a proper differential diagnosis to reach his conclusions. Therefore, based on the motion, briefs, and record cited therein, Select Comfort respectfully requests the Court exclude the expert reports and testimony of Dr. Chiodo.

Date: October 26, 2015.

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